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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,088	06/20/2003	Mark B. Knudson	14283.2US01	9155

7590 11/28/2005

Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903

EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/600,088	Applicant(s) KNUDSON ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

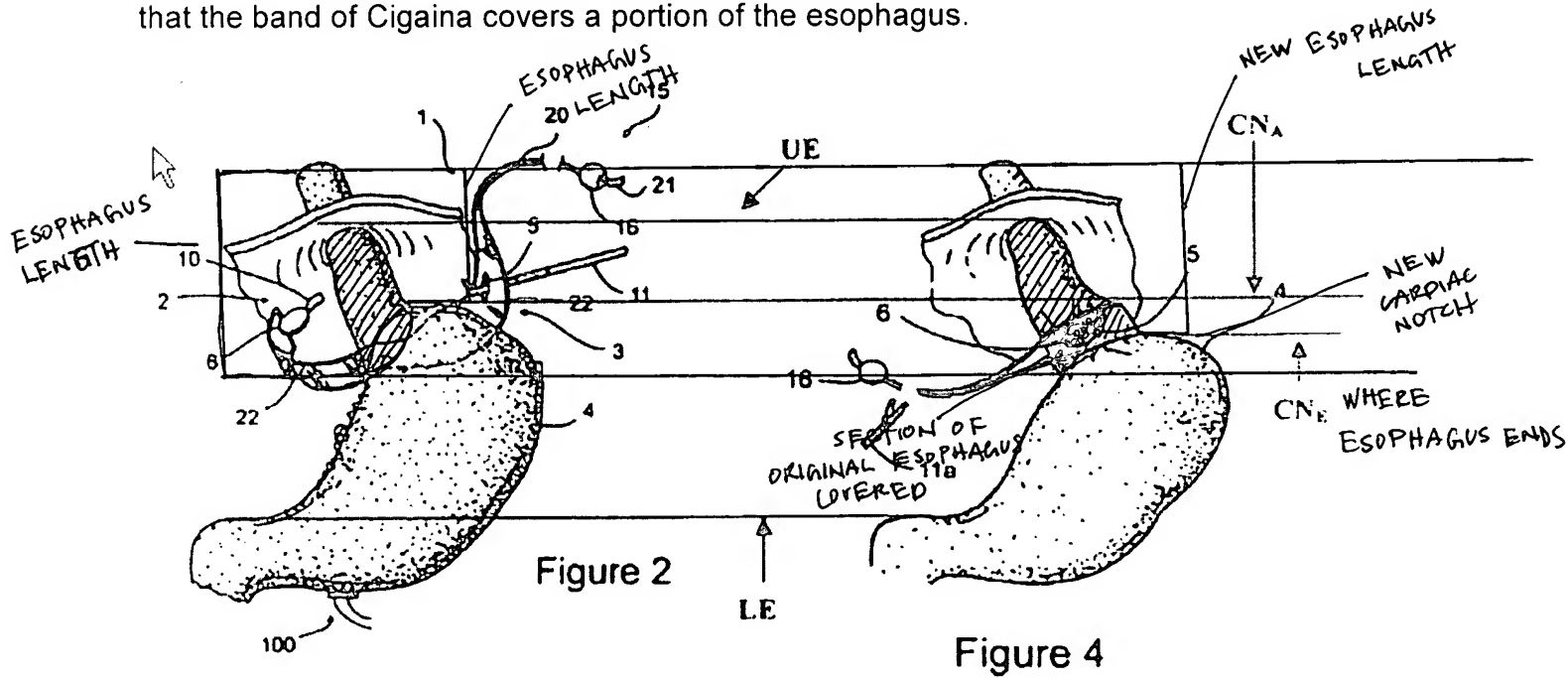
Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 31 August 2005 have been fully considered but they are not persuasive. The Applicant argues that no portion of the band of Cigaina resides above the cardiac notch. In the independent claims there is no limitation stating that the reducing element is place above the cardiac notch. The limitations only state that the reducing element reposition the cardiac notch. As seen in the figures of Cigaina the cardiac notch has been repositioned lower. The Applicant also argues that the band of Cigaina is not on the esophagus. The claims do not limit how much of the esophagus is in contact with the reducing element. Even if a small portion of the band of Cigaina is in contact with the esophagus it would read on the claim limitation. The drawings of Cigaina show the stomach at an angle from underneath. From this angle it can be seen that the band of Cigaina covers a portion of the esophagus.



Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5-7, 13, 15, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cigaina WO 01/41671 A2.

4. Cigaina teaches a method/apparatus for gastro-esophageal reflux disease (GERD) of a patient comprising: accessing a juncture of an esophagus and a stomach of the patient on a distal side of a diaphragm of the patient with the esophagus and a fundus of the stomach intersection at a cardiac notch located at an original cardiac notch position; placing a reducing element at the junction with the reducing element selected to reposition the cardiac notch to a repositioned cardiac notch position more distal to a lower esophageal sphincter of the patient and define an extended esophageal portion; the reducing element sized for the reducing element to be placed around both a distal portion of the esophagus and a proximal portion of the stomach, the placing including placing the reducing element around both the esophagus and the stomach to create the extended esophageal portion with the reducing element restraining formation of a gastric pouch between proximal and distal ends of the reducing element; wherein the placing includes selecting the element to be selectively adjustable along a length of the element to selectively adjust a volume of the element to form an extended esophagus portion between the original cardiac notch position and the repositioned

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cardiac notch position; wherein the element includes a material positioned loosely on the esophagus and fundus and the adjusting includes gathering and securing the gathered material along a length of the element; wherein the element is secured to either the esophagus or the stomach to restrict movement of the element relative to a final positioning of the element; wherein the securing includes providing selected areas of the element with tissue in-growth areas (see figs. 2-4); and wherein the element includes a securing member 6 for securing the element.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cigaina.

7. Cigaina disclosed the claimed invention except for a plurality of separate elements. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of separate elements since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

8. Claims 8-12 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cigaina in view of Forsell US 2002/0193842 A1.

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9. Cigaina teaches a method/apparatus according to the above rejected claims. It should be noted that Cigaina fails to teach placing an implant adjacent an esophagus of the patient to create a restricted region.

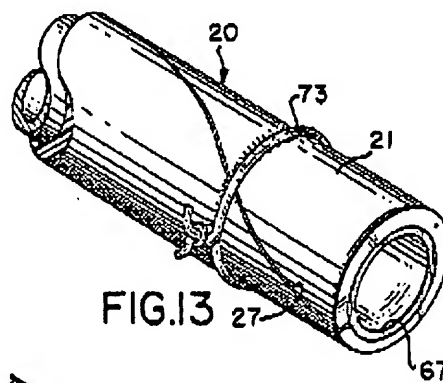
10. Forsell teach a device with a common implant for electrically stimulating the cardia sphincter to increase sphincter tonus. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the implant of Forsell to allow the patient at any time to control the treatment of heart and reflux disease when various needs arise over a day, so that the patient always is satisfied (pg. 1, [0005]).

11. Cigaina/Forsell teaches the method/apparatus as above, wherein the implant can be actuated to at least partially close the esophagus and abate reflux of contents of a stomach of the patient retrograde with the esophagus; wherein the implant includes actuation an artificial sphincter at least partially surrounding the esophagus to change states from an open state to an at least partially closed state, the artificial sphincter in the open state permitting substantially unimpeded food flow through the esophagus into the stomach, the artificial sphincter in the at least partially closed position at least partially closing the esophagus and abating reflux of contents of the stomach retrograde with the esophagus (pg. 4, [0046]); wherein the actuation of the implant is initiated by the patient (pg. 1 [0001]); and wherein the actuation of the implant is initiated by a controller operatively connected to electrodes and having an input operatively connected to organ sensors (pg. 1, [0012]).

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12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodapp 42188014.

13. Hodapp teaches an apparatus comprising: a reducing element formed of a bio-compatible material (rubber or urethane); wherein the element includes a slit along a length thereof and tie members (see figs 1-4 and 13). It should be noted that Hodapp fails to teach wherein the reducing element is dimensioned so as to surround the esophagus and at least a portion of the fundus. However, Hodapp teaches that the reducing element can be sized depending on the conduit that the element would be placed over (col. 5, lines 5-10). Therefore, it would have been obvious to one having ordinary skill in the art to use any size element including the size as limited by the claim depending on the dimensions of the conduit that the element will be used with.



Allowable Subject Matter

14. Claim 4 is allowable over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to teach or render obvious the overall claimed method for treating gastro-esophageal reflux disease (GERD) of a patient comprising: an element

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including a slit along a length thereof and adjusting includes altering a spacing of the slit.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed; and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER